REMARKS

Upon entry of this amendment, claims 1-6, 10, 16-18 and 20-32 will be pending and under consideration.

Claims 7-9 and 11-15 have been canceled in this response, claims 1-6, 10 and 16-18 have been amended, and new claims 20-32 have been added to more clearly claim the invention disclosed in the specification and claims as originally filed. In particular, claim 1 has been amended to recite a method for producing a controlled release matrix, comprising co-extruding through an extruder at least one pharmaceutically active agent and at least one starch, wherein the co-extruding is under sheer force, temperature and pressure conditions such that the starch in the extruded matrix is vitrified. Support for claim 1, as amended, is found on page 3, lines 9-15; page 4, line 26 to page 6, line 23. The amendments to claims 2-6, 10 and 16-18 were made to more clearly point out the claimed subject matter and support is readily found in the specification as filed. None of the amendments to these claims limit the scope of the claimed subject matter.

New claims 20-32 are supported in the specification as follows:

Claim	Support in Specification
20	page 4, lines 21-24
21	page 9, lines 26-28
22	page 6, lines 25-28
23, 24, 28-30	page 6, lines 22-24
25	page 3, lines 9-26; page 4, lines 4-5; and page 4, line 26 to page 5, line 18
26	page 5, line 24
27	page 6, line 21
31	page 4, lines 7-9; page 8, line 8
32	page 4, lines 7-9; page 11, line 24

No new matter is added by the amendments to the claims.

Rejection under 35 U.S.C. § 103(a)

Claims 5, 8, 9, 14 and 18 are rejected under 35 U.S.C. § 103(a), allegedly, as obvious over International Patent Publication No. WO 92/15285 by Lenz *et al.* ("Lenz"). According to the Examiner, the method of coextrusion for the production of a sustained-release composition comprising a starch/water mixture and an active ingredient would have been obvious in view of the teachings of Lenz. Applicants respectfully disagree with the Examiner's rejection.

Preliminarily, we note that in the text of the Office Action, the Examiner only rejects claims 5, 8, 9, 14 and 18 under 35 U.S.C. § 103(a); however, in the Office Action Summary, claims 1-18 are listed as being rejected. Furthermore, from reading the text of the Office Action dated May 6, 2003 and the Office Action dated February 11, 2004, it is unclear whether the Examiner has maintained his rejection under Section 102(b) and/or Section 103(a). Therefore, Applicants will address both the novelty and non-obviousness of the presently claimed subject matter in view of Lenz.

A careful reading of Lenz reveals that Lenz teaches compositions comprising (i) a matrix comprising starch which has been processed under shear at temperatures of about 80°C to 240°C, preferably to a specific endothermic transition just prior to oxidation and thermal degradation, and (ii) a pharmaceutically active ingredient. Note that the active ingredient is not processed with the starch but is merely combined with the starch after processing. See Lenz at page 11, lines 13-25; at page 14, lines 16-25 and the Examples. Moreover, the processed starch, called molecularly dispersed starch or MDS in Lenz, is not stiff or glassy, but rather is soft and rubbery. Applicants invite the Examiner's attention to Example 1 of Lenz, at page 28, lines 31-38, which teaches that the MDS obtained by extrusion of the potato starch is soft and rubbery.

Further, the only passage of Lenz that concerns co-extrusion of a pharmaceutically active agent and a starch is in Example 18, the only example out of 33 examples. Example 18 teaches co-extrusion of starch that was already processed according to the teaching in Lenz, *i.e.*, MDS, an active agent (clotrimazole) and talc. However, the resulting extruded product is a foamed product, which does not provide for predetermined and reproducible release of the agent, *i.e.*, controlled release, but, rather, results in immediate release. Thus, the only product made by co-extrusion taught by Lenz is an immediate release product, not a controlled release product.

Thus, Lenz teaches a product produced by a method of combining a pharmaceutically active agent with processed, molecularly dispersed starch (MDS), which MDS is rubbery and soft, as well as an immediate release product made by co-extruding MDS and a pharmaceutically active agent.

In complete contrast, the presently claimed invention relates to a controlled release matrix comprising starch and a pharmaceutically active agent, wherein the starch and active agent were co-extruded and the starch in the extruded matrix is vitrified (not rubbery or soft), as well as a method for producing the same by co-extruding starch and a pharmaceutically active agent, wherein the starch in the extruded matrix is vitrified.

In order for a reference to anticipate a claim, each and every element of the claim must be disclosed in that one reference. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d

1565 (Fed. Cir. 1985). "Anticipation under Section 102 can be found only if a reference shows exactly what is claimed . . ." *Structural Rubber Prod. Co. v. Park Rubber Co.*, 749 F.2d 707 (Fed. Cir. 1984). As Lenz does not disclose exactly what is claimed, *i.e.*, Lenz does not disclose a method for producing a controlled release matrix by co-extruding starch and an active agent or a controlled release matrix wherein the starch and active agent are co-extruded and wherein the starch in the extruded matrix is vitrified, Lenz does not anticipate the claimed invention.

Further, there is nothing in Lenz that suggests such claimed methods and compositions relating to co-extrusion. In fact, Lenz actually teaches away from the claimed invention since in the only example in Lenz of co-extrusion, Lenz co-extrudes MDS with an active agent, which results in the formation of an immediate release matrix, not a controlled release matrix.

Therefore, Applicants submit that Lentz neither anticipates or renders obvious the claimed subject matter, and, therefore, respectfully request that the rejections in view of Lenz be withdrawn.

CONCLUSION

Applicants respectfully request that the above-made amendments and remarks of the present response be entered and made of record in the file history present application. Applicants submit that the presently pending claims meet all requirements for patentability and respectfully request allowance and action for issuance.

Applicants request that the Examiner call the undersigned at (212) 326-3921 if any questions or issues remain.

Respectfully submitted,

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Enclosures